

REMARKS

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 are pending in the present application. The following objections and rejections are at issue and are set forth by number in the order in which they are addressed:

1. The specification and claims 27 and 28 are objected to;
2. Claims 23 and 28 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite; and
3. Claims 1, 9, 14-20, 23, 26-36, 38, 40 and 42 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description.

Applicant notes that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future.

1. Objections

The specification has been amended consistent with the Examiner's recommendation. Claims 27 and 28 have been canceled. Accordingly, the objection to those claims is moot.

2. The claims are definite

Claims 23 and 28 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claim 23 has been amended to specify that the plant comprises the vector of claim 15. Claim 28 has been canceled. Accordingly, the rejections are now moot.

3. The claims are supported by an adequate written description

Claims 1, 9, 15-20, 23, 26-36, 38, 40 and 42 are rejected under 35 U.S.C. §112(1) for failing to comply with the written description requirement. Applicants respectfully disagree with the Examiner's rationale for the rejection for the following reasons.

First, the Examiner states that “the nucleic acids of the claimed are described by function only. Applicant has not described the composition and structure of *H. glycines* embryonic lethal phenotype genes.” Applicants respectfully state that this statement is incorrect. Applicants again note that this application provides many specific examples of *Heterodera glycines* that fall within the scope of the claims. The Examiner is referred to Table 1, pp. 35-37, which specifically lists suitable sequences corresponding to *Heterodera glycines* embryonic lethal phenotype genes and to Examples 1, 2, and 3, which describe the cloning of such genes from *Heterodera glycines*. The structure (i.e., the sequence) and the function of these sequences is described. The sequence is the structure.

Second, the Examiner states that the “specification fails to describe a representative number of conserved genes having lethal RNAi phenotypes in *H. glycines*. Unlike the free-living nematode *Caenorhabditis elegans*, the *H. glycines* genome is not fully sequenced and is not well characterized with a number of lethal genes identified through experimental methods. The specification only describes sequences for *H. glycines* for msp, RNA polymerase II and chitin synthase RNA. Therefore, neither the specification nor the prior art describes a representative number of genes essential for *H. glycines* survival for the production of soybean cyst nematode resistant plants as claimed in the instant application.” Again, Applicants respectfully disagree. Whether or not there is an adequate written description needs must be analyzed with respect to the level of skill in the art. The specification, at pages 35-37, provides specific examples (including sequences) of genes falling within the scope of the claims and identifies other genes that also fall within the scope of the claims. The level of skill in this art is high. A person of ordinary skill in the art would have several years of post-doctoral research experience. One of skill in the art would be able to either use the exemplified and identified genes or clone additional genes within the scope of the claims. Many such genes from other organisms have been identified as described in the specification. One of ordinary skill in the art would have been able to clone corresponding genes from *H. glycines* and use them in the claimed invention.

The Examiner’s reliance on the *Eli Lilly* decision is misplaced. The Federal Circuit has specifically recognized that the written description requirement does not require that applicants recite the precise structure, formula, chemical name, or physical properties of a chemical entity. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003). Instead, written

description “requires assessment from the viewpoint of one of skill in the art.” *Id.* at 1320. The Federal Circuit further explained that the “written description requirement does not require the applicant to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Id.* at 1321.

The holding of the Federal Circuit in *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) is far more pertinent to the facts of the present application than *Eli Lilly*. In *Capon*, the Federal Circuit specified that it was not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect was sufficiently demonstrated to characterize a generic invention. *Id.* at 1359. The Federal Circuit, holding that the claims at issue were supported by an adequate written description, explained that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. *Id.* The Federal Circuit held that it is “well recognized that in the ‘unpredictable’ fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Such a decision usually focuses on the exemplification in the specification.” *Id.* The Federal Circuit then found that the inventors had provided both specific and general examples exemplifying the claimed invention. *Id.*

As in *Capon*, the present inventors have provided both specific examples of genes within the scope of the present claims as well as general teachings of how to identify and isolate other genes useful in the claimed invention. Given the high level of skill in the art, this description is adequate. In addition to the specific examples of sequences provided in the specification, a person of ordinary skill in the art is able to easily screen the large number of known genes for *H. glycines* embryonic lethal phenotype genes. As described in the specification, the art is replete with evidence of *C. elegans* embryonic lethal phenotype genes, and these have been used by others in the dsRNA field to identify related genes predicted to encode the same or similar proteins in other eukaryotic organisms such as *D. melanogaster*, and in this case, *H. glycines*. Based on these abilities and the level of skill in the art, the inventors have sufficiently demonstrated with at least three examples of lethal phenotype genes, that targeting these genes

for dsRNA mediated gene suppression using sequences derived from the *H. glycines* lethal phenotype genes functions to suppress the targeted gene and thus, suppress the viability of the *H. glycines* consuming such dsRNA molecule. Furthermore, the claims do not read on each and every possible sequence of a homolog of a lethal phenotype gene but only on the embodiments that result in failure of the targeted nematodes to proliferate. The claims are allowable because the specification provide written description for the genus of *H. glycines* genes than can be targeted for suppression by providing in the diet of the nematode a dsRNA targeting for genetic inhibition a nematode embryonic lethal phenotype gene, with the result being that the nematode ingesting such dsRNA does not proliferate.

Third, the Examiner cites Hussey et al., *Braz. J. Plant Physiol.*, 14(3):183-194(2002) as reporting a large number of plant nematode parasitism genes encoding novel proteins are identified but that over 70% have no homology with functionally annotated genes in the databases. The present claims are limited to the use embryonic lethal phenotype genes. Applicants respectfully submit that the teachings of Hussey et al., which address parasitism genes, are not applicable to the present claims which are directed to the use of embryonic lethal phenotype genes. Moreover, due to the high level of skill in the art and the teaching of the specification, a person of ordinary skill in the art is able to easily screen the large number of known genes for a *H. glycines* embryonic gene.

As such, one of skill in the art would conclude that the Inventors were in possession of the necessary common attributes possessed by the members of the genus, and therefore the instant specification meets the written description requirement for these claims. The Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Each rejection of the Office Action mailed September 18, 2007 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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